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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,673	05/08/2001	Jonathan M.J. Derry	3198	3258
22932	7590	11/25/2003	EXAMINER	
IMMUNEX CORPORATION LAW DEPARTMENT 51 UNIVERSITY STREET SEATTLE, WA 98101			SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Applicati n No. 09/851,673	Applicant(s) DERRY ET AL.	
	Examiner Carolyn L Smith	Art Unit 1631	

--The MAILING DATE of this communication appears on the cover sheet with the corr spond nce address --

THE REPLY FILED 12 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☒ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 26.

Claim(s) rejected: 25-39.

Claim(s) withdrawn from consideration: _____.

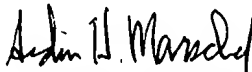
8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: The previous claims in this application's prosecution were directed to a method for identifying a compound that inhibits binding whereas the newly proposed amended and new claims are directed to a method for determining an effect of a test compound on binding which is a new issue. Contacting a test compound with the NEMO and CYLD polypeptides and then determining effects (as stated in the newly proposed amended and new claims) also differs from the previous claims in this application's prosecution which involved mixing the test compound with NEMO and a CYLD binding partner and determining the presence of inhibition. These new issues would require further consideration and/or search.

There does not appear to be written support for "contacting a test compound with the NEMO polypeptide and the CYLD polypeptide" (proposed amended claim 26, line 17, and proposed claim 40, line 8). The specification mentions contacting cells with candidate molecules (page 15, lines 3-4), but not contacting the test compound with the NEMO and CYLD polypeptides. There does not appear to support for the phrase in step (ii) (proposed claim 26 (lines 18-24) and proposed new claim 40 (lines 9-15)) which includes "determining the effect of the test compound on the binding...less than about 50% of the binding of the NEMO polypeptide to the CYLD polypeptide in the absence of the test compound, the test compound inhibits the binding of NEMO and CYLD." This phrase involves the comparison of the amount of binding of the NEMO and CYLD polypeptide whereas the specification only provides support for comparison of cell activity (page 15, lines 3-5). Also this phrase includes "less than about 50%" whereas the specification only provides support for "at least 50%" on page 12, lines 25-28.

Continuation of 5. does NOT place the application in condition for allowance because: Proposed claims 40-42 are new claims with new issues that would require a further search.

If the amendment had been entered, then the informality objection to claim 26 (missing the word "and" in the Markush group) would be removed. Also, the lack of scope of enablement rejection (referring to the identification of compounds that inhibit the binding activity of NEMO and CYLD polypeptides via fragments), lack of enablement rejection (referring to the unpredictability of knowing what fragment involved would still allow the NEMO and CYLD polypeptides to be biologically active), and lack of written description rejection (referring to "fragments", "comprising" and "consisting essentially of") would be maintained as stated in the FINAL office action, mailed 8/7/2003.


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